Laboratory Bulletin

Utah Department of Health

Laboratory Bulletin

Division of Epidemiology and Laboratory Services
Bureau of Laboratory Improvement
Web page: http://health.utah.gov/els/labimp **November 2002**

Introducing

Norm Brown	Mycobacteriology
Sharon Elison	Tech Services
Tom Ellevold	Virology
Zita Vavrin	Virology

NOTEWORTHY

☛ **NO! TO CLOT ACTIVATOR TUBES FOR BLOOD BANK TESTS:** According to Diane Avinoso, MPH, MT(ASCP), manager for the transfusion service at Oregon Health and Science University in Portland, you cannot use clot activator tubes for blood typing or cross matching.

Ms. Avinoso responded to the question in the September, 2002 issue of MLO. If the separator tube uses gel for the separation, the gel interferes with direct antibody testing (DAT) and auto control testing by producing a false positive. The tubes without gel can't be used for antibody screen or DAT as the silica particles interfere with test results. Ms. Avinoso said the serum from separator tubes can be used for serologic testing, but the blood cell layer is contaminated and causes trouble with other blood bank tests.

To solve the problem of waiting for blood to clot in a standard clot tube, Ms. Avinoso said labs are using EDTA blood in transfusion facilities as they are preferred for Ortho gel and Immucor solid phase assays. They are also preferred for DAT and most fetal-maternal bleed-screening tests.

☛ **BNP TESTING:** What? For diagnosing congestive heart failure, the up and coming test is definitely B-type natriuretic peptide (BNP). Triage makes a rapid test to add to the "rule out heart attack on chest pain in the ER" armamentarium. This naturally secreted hormone is released from the heart ventricles as pressure to the cardiac wall increases. The hormone half life is about 20 minutes making it a great candidate for current not past heart damage.

☛ **TRACE BLOOD ON A UA DIPSTICK:** Numerous substances can interfere with a urine dipstick test for blood – most notably – ascorbic acid. Check your package insert to find other problems inherent in the test.

The urine reagent strips are very sensitive. They can detect the equivalent of 2 to 3 RBCs per high-

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power field. But the concentration of blood on the strip (trace or 4+) has never been related to the cause or seriousness of a disease. After checking with the patient for anything that may be interfering with the test, any amount of blood should be reported. Blood in the urine is often intermittent – even if the patient has a lethal disease. A positive urine dipstick is not diagnostic, just a screening test that warrants further investigation. Even a "trace" on the pad (read within the manufacturer's appropriate time frame) is a positive test result.

☛ **FIELD TESTS FOR ANTHRAX:** The September, 2002 MLO reported CDC sent a memo to more than 250 federal agencies, firefighters, police and local officials advising they stop buying / using the field tests for anthrax. CDC reports the tests are unreliable. They give false positive and false negative results. Sending suspect environmental anthrax specimens to a CDC approved lab (such as your state public health lab) will provide accurate test results in about 6 hours.

☛ **ANTIBIOTICS INTERFERE WITH URINE DRUG SCREENS:** Researchers at Brigham and Women's Hospital in Boston studied the effects of 13 quinolone antibiotics on 5 commercial opiate screening tests in 6 healthy volunteers. At least one antibiotic from the quinolone family caused false positive opiate test results in all five assay systems. The authors conclude that greater attention should be focused on cross-reactivity of quinolones with opiate immunoassays.

☛ **REPORT THE STORAGE / USE OF POTENTIAL BIOTERRORISM ORGANISMS**: The Public Health Security and Bioterrorism Preparedness and Response Act, passed after 9/11, requires facilities to report whether or not they have designated "select agents or high consequence livestock pathogens and toxins". Laboratories were required to report by September 10. For complete information check the following website: www.cdc.gov/od/ohs/lrsat/guidance.htm

☛ **SETTING REFERENCE RANGES:** A laboratorian asked if every lab needs to set their own reference ranges for each test or could they use "values" from the literature. D. Robert Dufour, MD, Chief of Pathology of the Veterans Affairs Medical Center in Washington, DC answered in the August 2002 issue of MLO. He said NCCLS states to set your own reference limits with "reasonable accuracy" you need to test 120 individuals. If you have a test whose "normal" ranges may be age dependent (lower or higher for children or the elderly), you test 120 persons from each group. Unless you are a very large corporation, this method is not feasible.

Dr. Dufour says most facilities do as his does - validate published ranges with 20 individuals from your patient population. If no more than 2 results are outside the published ranges, you can use them. However, he quoted a study done by our own Dr. Crapo at LDS hospital comparing blood pO_2 results at sea level to those at 4,500 feet. Using 339 "normal" adults, Dr. Crapo discovered oxygen partial pressure decreases with increasing age. Just remember, no published range (literature, manufacturer, other laboratories' studies in your area) will always meet what you need for your patient population. But generally, they do if you validate them.

☛ **MANAGING WOMEN WITH ABNORMAL PAP RESULTS**: There was a review of an article "Wright TC, Cox JT, Massad LS, et al. 2001 consensus guidelines for the management of women with cervical cytological abnormalities (AGC).JAMA.2002;287:2120-2129" in the August 2002 issue of CAP Today. A couple of key points from the article are:

Reflex Human Papilloma Virus (HPV) DNA testing is preferred when the Pap is collected in a liquid-based system.

Managing the treatment of women with AGC by repeat Pap testing is unacceptable.

For the complete article text and additional information go to the American Society

Colposcopy and Cervical Pathology Web site at www.asccp.org

☛ **COAG REAGENTS - CHECK:** If you are using the MLA 750 or the MLA 800 with DADE reagents for your coagulation testing, please **call DADE technical support immediately**. There may be a change in which ISI value you should be using. The value you are using may adversely affect your patient prothrombin test results. There is no listing for which ISI value to use for the MLA 750 in the DADE package insert. Some labs have been given the wrong information by DADE technical representatives as to which value to use.

☛ **TOLERANCE TEST WHEN FASTING BLOOD SUGAR IS HIGH?:** William E. Winter, MD, of the Department of Pathology at the University of Florida in Gainesville responded to this question in the August, 2002 issue of CAP Today. In 1997 the American Diabetes Association changed existing recommendation for diagnosing diabetes.

1. Fasting glucose of 126 mg/dL or greater.
2. Random plasma glucose of 200 mg/dL or greater with symptoms.
3. A two-hour plasma glucose on an oral glucose tolerance test (OGTT) is 200 mg/dL or greater.

Further, if there is no ketoacidosis or hyperglycemic nonketotic coma at initial presentation, hyperglycemia must be confirmed by testing on two separate occasions before diagnosing diabetes.

There is no need for the old 3 to 5 hour OGTT. There is no need for a glucose test one hour after administering the glucose dose. Fasting, random or two hour postprandial glucose is all that is necessary to diagnosis diabetes.

FROM THE PATIENT'S CHART

"Patient has chest pain if she lies on her left side for over a year."

☆ Feature: ☆

VANCOMYCIN RESISTANT STAPH AUREUS - REVISITED

Another case of Vancomycin-resistant *Staphylococcus aureus* (SA) from Pennsylvania has the health care officials very worried.

The October 11, 202 MMWR has the details on the second case in the US. (www.cdc.gov/mmwr/preview/mmwrhtml/mm5140a3.htm)

The Clinical Microbiology Reviews, July 2002, contains useful information on resistant SA.

- NCCLS minimal inhibitory concentration (MIC) interpretation ranges =
  Susceptible: ≤ 4 µg/mL
  Intermediate: 8 to 16 µg/mL
  Resistant: ≥ 32 µg/mL

- Only 25% of microbiology laboratories world wide (using disk diffusion) correctly reported a glycopeptide-intermediate *S. epidermidis* correctly.

- Vitek software before 1999 incorrectly reported vancomycin MIC above 4 for SA. The system did not read levels above 4, so it reported all readings above 4 as resistant with no intermediate differentiation.

- E test MIC is the "gold standard". But to detect resistant SA in a mixed population (some sensitive, some resistant), the test may have to be incubated a full 48 hrs. Some inconsistencies were reported even with this method.

- Screening isolates on vancomycin-containing media may detect even low levels of resistance.

- CDC susceptibility recommendations =
  Primary testing: incubate at least 24 hrs.
  Do not use disk diffusion tests.
  Confirm susceptibility with MIC.
  Send any SA with an MIC of ≥ 4 µg/mL to CDC.

- Vancomycin use must be limited to situations deemed appropriate by current CDC guidelines.

- So far, all resistant strains have been in acute-care hospital patients only.

- It may take at least 30 days on vancomycin therapy for SA to develop resistance.

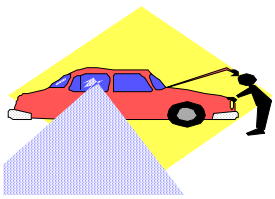
- Vancomycin can be recovered from intermediate and resistant SA cell walls.

- For any suspect resistant SA, the coagulase test should be incubated more than 4 hrs.

- All resistant SAs have been susceptible to tri-methoprim-sulfamethoxazole and tetracycline.

- New antibiotics, quinupristin-dalfopristin and linezolid, may be useful in managing patients with resistant SA.

"If past experience with multidrug resistant organisms is any indicator, the problem of vancomycin-resistant staphylococci will only grow in the future. However, heightened awareness of the issues and strict adherence to current guidelines for vancomycin use and infection control practices may help limit the impact of these organisms."



CLIA BITS:

ADDITIONAL WAIVED TESTS:

° Meridian Bioscience ImmunoCard STAT! H. pylori Whole Blood Test

° Phamatech QuickScreen One Step (multiple drugs of abuse)

° Serim Pyloritek VP Test Kit for *H. pylori*

° Genzyme OSOM Strep Ultra Test – 25 Test Kit Size for group A Strep

° Stesans Maybe?Mom Mini Ovulation Microscope for saliva fern test

° O2 Unlimited Donna Ovulation Tester for saliva fern test

° Biotest Hemoglobin Measuring System for Hgb

° Diagnostic Chemicals ImmunoDip urinary Albumin Test

° Polymer Technology Systems Bioscanner 2000 PTS Panels Ketonel Test Strips for blood ketone

° Polymer Technology Systems Bioscanner Plus PTS Panels Lipid Panel Strips for cholesterol, HDL cholesterol and triglycerides

° Polymer Technology Systems CardioCheck PA PTS Panels Lipid Panel Strips for cholesterol, HDL cholesterol and triglycerides

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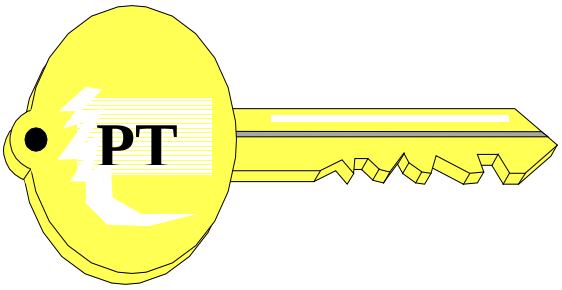
HIPAA

The deadline for compliance with the Transaction & Code Set Standards of the Health Insurance Portability & Accountability Act (HIPPA) was October 16. If you filed for a one-year extension under the Administrative Simplification Compliance Act (ASCA), you have another year to comply.

You can get current information at the CMS website (www.cms.hhs.gov/hipaa/hipaa2). You can email at askhipaa@cms.hhs.gov. You can call the HIPAA Hotline at (410) 786-4232.

Equals

"100 Senators: Not 1 decision"



Enrollment time is here. Don't forget about those moderately complex tests that are seasonal (influenza, etc).

Make certain the module you choose fits your instrument. We had one facility enroll in a blood gas module whose matrix did not match their instrument. They failed two events before discovering the error.

Make certain you enroll in a module that gives you 5 samples each event. We had one facility enroll in a module that sends 2 specimens for several different tests. Many companies have 2 sample modules to meet accrediting agency requirements for doing proficiency testing on CLIA waived tests. Don't order one of those modules for a moderately or highly complex test.

Safety Tips

Laboratory Liability:

Barbara Harty-Golder, MD, JD wrote an article for the September issue of MLO about making your facility "child-safe".

State law has jurisdiction, but juries always feel sorry for the "victim". Few for-profit facilities are ever viewed as "victim". If you have a phlebotomy area, children will run loose. It is the parent's responsibility to manage their children, but your facility is liable for any injury sustained onsite.

Even your lounge area should be "child proof". We have heard many stories about children doing things no one thought possible. What about the child who ate the inoculated agar plates for gonorrhea culture because she thought they were chocolate candy? A child was able to reach into the safe sharps container on the counter and extract used syringes to play with in the exam room! Prepare waiting rooms – cover electrical outlets; stabilize furniture so that it won't tip over; coffee makers can spill hot liquid onto a child (they can pull it over from the cord plugged into the outlet); etc.

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Can Formalin destroy prions that cause "Mad Cow Disease"? Refer to *Biosafety in Microbiological and Biomedical Laboratories, 4th edition* (CDC) and *Infection Control Guidelines for Transmissible Spongiform Encephalopathies* (WHO). Additional information is on the CDC website (www.cdc.gov) by searching on "CJD".

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Low staffing levels may increase chances for needlestick injuries. "Nurses (and any phlebotomist) potentially unfamiliar with safe use of sharps were often forced to become proficient while their workloads were increasing in other ways. Nurses who took on routine blood draws or intravenous insertions as a new task in the previous year were almost twice as likely to sustain injuries,: said Sean Clarke, PhD, RN, associate director of the Center for health Outcomes and Policy Research at the University of Pennsylvania School of Nursing, which conducted a study of 2,278 nurses.

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The United States Department Of Transportation revised its standards for infectious substances transport on August 14, 2002. The standard was effective October 1. The RSPA-98-3971 (HM-226)

regulation entitled “Hazardous Materials: Revision to Standards for Infectious Substances” is available at http://hazmat.dot.gov/67fr-53118.pdf.

Revisions are “transportation requirements for infectious substances, including regulated medical waste, to: adopt defining criteria and packaging requirements consistent with international standards; revise the current broad exceptions for diagnostic specimens and biological products; and authorize bulk packaging options for regulated medical waste consistent with requirements in international standards and DOT exemptions.”

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ABBOTT RECALL

The Food and Drug Administration (FDA) had Abbott recall 32 lots of their LCx *Neisseria gonorrhoeae* testing kits as they may give false negative results. The affected lot numbers were distributed between January 11 and June 24 of this year. The following lots failed to meet specifications when tested and were recalled: 84073M400; 84075M400; 84142M300; 84146M300; 85487M200; 87007M400; 87103M400; 87243M100; 87377M200; 87899M200; 87905M200; 88097M300; 88105M300; 88107M300; 88439M200; and 88439M201.

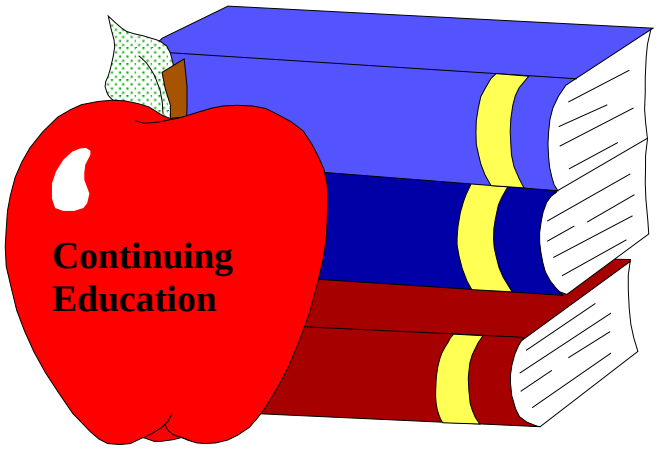
Patients testing negative with these lots should be retested. For the entire FDA recall notice go to http://www.fda.gov/bbs/topics/NEWS/2002/NEW00832.html.

IF YOU LOVE SOMETHING, SET IT FREE

IF IT RETURNS TO YOU, YOU HAVEN’T LOST IT

IF IT DISAPPEARS AND NEVER COMES BACK, THEN IT WASN’T TRULY YOURS TO BEGIN WITH

Author unknown



1. UPH Lab - BLI

Quality Assurance (QA) Tools:

QA for moderate/high complexity labs and QA for waived labs documents are now online at http://health.utah.gov/els/labimp. Click on Clinical Laboratory Certification (CLIA). These documents were prepared by Lab Improvement to aid facilities provide quality testing. They could also help you prepare for a CLIA inspection.

Lending Library Additions:

U-77: *Identification of common Aspergillus species* by Maren A. Klich from the USDA. This book was published in 2002 with excellent colored culture photos, black and white microscopic photos, and identification by species.

U-78: *Hemolytic Uremic Syndrome*, 43 minute video by the Lois Joy Galler Foundation (1995).

U-79: *Urinalysis – The Inside Story: Evaluation*, 25 minute video by NCCLS.

2. NLTN Lending Library Additions

West Nile Virus Update, satellite broadcast 8/8/02.

A New Era in Newborn Screening – Saving Lives, Improving Outcomes, satellite broadcast 9/19/02.

3. NCCLS

EP-12A: *User Protocol for Evaluation of Qualitative Test Performance*

EP19-R: *A Framework for NCCLS Evaluation Protocols; A Report*

EP21-P: *Total Error for Clinical Laboratory Methods*

X3-R: *Implementing a Needlestick and Sharps Injury Prevention Program in the Clinical Laboratory; A Report*

M29-A2: *Protection of Laboratory Workers from Occupationally Acquired Infections*

GP5-A2: *Clinical Laboratory Waste Management*

M27-A2: *Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts*

M 38-A: *Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi*

M40-P: *Quality control of Microbiological Transport Systems*

4. CME/CMLE Credits from API

Sign up for free credits under “Continuing Education Activity” on their website, www.api-pt.com.

1999 British GCSE exam results from 16 year olds:

Q: What is terminal illness?

A: When you are sick at the airport.